IMPORTANT INFORMATION: File this in your TPS records

TPS™

Total Performance System Consoles

REF 5100-1 & 5100-1A Console

REF 5100-50 & 5100-50A Irrigation Console

User's Guide

Includes setup, safety, repair, and warranty information for the Stryker Total Performance System.

For answers to questions about other equipment, see the information supplied with that equipment.

CE 0197

stryker®

Version

4.x

US Patents D398,598; D415,134; 5,543,695; 5,689,159; 6,017,354; 6,025,683; 6,045,564; 6,329,778 and other patents pending

10/05

5100-001-709 Rev-F

Instruments
4100 E. Milham
Kalamazoo, Michigan
(USA) 49001
1-800-253-3210
1-269-323-7700

www.stryker.com

European Authorized Rep:
RA/QA Manager
Stryker France
ZAC Satolas Green Pusignan
Av. de Satolas Green
69881 MEYZIEU Cedex
France

Contents

Software License Notice 3

Where to Find Answers 4

Warning, Caution, Note Defined 4

Important Safety Instructions 5

System Overview
Symbol Definition 6

Operating Instructions
Connecting the Equipment 7

The Control Screen
TPS Start-Up Screen
No Handpiece Detected Screen 8

Functions of the Control Screen
Elements of the Control Screen 9

Select Your System Settings
Standard Features 10

Quick Reference Guide (Icon Definition) 11

Handpiece Screens

Saw Handpiece Screen (TPS Oscillating and Sagittal Saws) 12

Rotary Handpiece Screen
(TPS Universal and MicroDrills & TPS MicroDriver) 13

Stryker Endoscopy and Leibinger Handpiece Screen
(SE5 hand-controlled Endo Shaver, QuadraCut Shaver, QuadraCut Bone Plug,
and QuadraCut Small Joint, Hummer 4, Formula, 6K Micro, 12K Micro) 14

Other Screens

Main Option Screen 15
System Information Screen 16
Handpiece Adjustment Screen 17
Console Adjustment Screen 18
Footswitch Adjustment Screen 19
Footswitch Button Mapping Screen 20
Handpiece Button Mapping Screen 21
Surgeon Preference Screen 22
Messages and Error Messages 23

Specifications 24
Compliance Statements 24

Declaration of Conformity 25

Guidance and Manufacturer's Declarations 26-28

Repair/Loaner Program
Limited Warranty 29

Software License Notice

Stryker® TPS™ Surgical Tool System products contain software that is installed in the products by Stryker Corporation. Stryker Corporation owns this software; this software is never sold. Each sale of a software containing product is not a sale of such software; it includes only a license to use the software in the product in which the software was initially installed.

Any license granted by Stryker Corporation to use the software contained in its; products does not give the licensee the right to copy, alter, disassemble, reverse engineer, create derivative works of such software or to use such software in either original or modified form in any product other than the Stryker Corporation product in which the software was initially installed by Stryker Corporation.

© 2003, Stryker Corporation

Where to Find Answers

When you have questions about your Stryker TPS products, there are several places to find the answers.

In this book

Use this book to set up your system and select console options. This book also contains information on system safety, repair, and component warranty.

In TPS component instructions

For answers to questions about any TPS handpiece, attachment, or component , see the information supplied with that component. A copy of *TPS Cleaning, Maintenance and Sterilization Recommendations* is also supplied with each component.

From your Stryker Sales Representative

If you can't find an answer in any of the materials provided or you have questions about other Stryker Instruments products, call your Stryker Sales Representative.

From Stryker Customer Service

Please contact our Customer Service Department to order product information literature, a cutting accessories guide, additional TPS maintenance manuals, and component instructions by dialing 1-800-253-3210. Outside the U.S.A., contact your nearest Stryker subsidiary.

See the *TPS Cleaning, Maintenance, and Sterilization Recommendations* booklet for care information.

Warning • Caution • Note

This symbol is used to alert the reader to important safety and precautionary information. When displayed on the actual device, it refers the user to accompanying documents.

Please read this manual and follow all instructions carefully. The words WARNING, CAUTION and NOTE carry special meanings and should be carefully reviewed.

WARNING: The personal safety of the patient and/or user may be involved. Disregarding this information could result in injury to the patient and/or operating room staff.

CAUTION: These instructions point out special service procedures or precautions that must be followed to avoid damaging the instrument.

NOTE: This provides special information to make maintenance easier or important instructions more clear.

⚠ IMPORTANT SAFETY INSTRUCTIONS

WARNING: The personal safety of the patient and/or user may be involved. Disregarding this information could result in injury to the patient and/or operating room staff. Read and understand the following warnings.

SYSTEM SAFETY

- Prior to each use, operate system components and inspect for damage. DO NOT use if damage is apparent. Take special precautions regarding electromagnetic compatibility (EMC) when using medical electrical equipment like the TPS Console. Install and place the console into service according to the EMC information in this manual. Portable and mobile RF communications equipment, such as wireless phones, can affect the function of the console.
- Use only Stryker approved accessories. Other accessories may result in increased emissions or decreased immunity of the system. Contact your Stryker sales representative for a complete list of accessories. DO NOT modify any accessory. Failure to comply may result in patient and/or operating room staff injury.
- DO NOT modify ground of power cord.
- Equipment not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- The Stryker Total Performance System is designed to be used by persons familiar with surgical procedures. Misuse may cause injury to both patient and system components. Prior to each use, system components should be inspected for damage. DO NOT use if damage is apparent.
- Use only Stryker TPS components and accessories unless otherwise specified.
- Clean and sterilize handpieces and accessories before first and every use.
- Use of safety glasses by user and operating room staff is recommended to prevent eye injuries.

HANDPIECE SAFETY

- **Read this booklet and the information supplied with your TPS components. Component instructions provide specific safety information. Refer to the instructions supplied with Stryker Endoscopy handpieces when using those handpieces in conjunction with the TPS console.**
- DO NOT attempt to change a saw, bur, or drill while handpiece is running.
- Stryker handpieces which fail due to long life and/or nose bearing failure may allow foreign matter to migrate or emit from the distal tip of the handpiece.
  Fluid may leak into the surgical site, such that measures may be required, per the physician's discretion, to protect the patient from infection.
- Never rest handpiece on the patient. Improper handling of a handpiece could result in damage or burns to tissue.
- Do not place a TPS handpiece near or on a magnetic pad or tray. The magnetic field can simulate a Universal Handswitch and may cause the handpieces to run inadvertently.
- DO NOT modify any bur to fit the handpieces. Use only Stryker approved burs. Other burs may not fit properly in the handpiece. During use they may come out of the handpiece or bend which would result in damage to tissue in the surgical site due to loss of control of the bur.
- Burs and blades are intended for single use only.
- Excessive pressure, such as bending or prying, may cause accessory to bend or break and cause tissue damage to patient and/or operating room staff.
- Heavy sideloads and/or long operating periods occasionally will cause overheating of the distal tip and the body of handpieces to the point where the handpiece is uncomfortable to hold or causes injury to the patient.
- If the recommended duty cycle is not followed, the handpiece may overheat and cause injury to patient and/or operating room staff. See the *Duty Cycle* information supplied with each handpiece.
- Excessive pressure, such as bending and/or prying with a bur, may cause the bur to bend or fracture. If operated at a high speed, it is possible that the bur will bend yet further. This could result in damage to tissue in the surgical site, handpiece vibration that causes lost tactile control, or breakage of the bur such that the broken piece would be ejected at a high velocity endangering the patient and/or operating room staff. It is therefore recommended that safety glasses be used.
- Excessive pressure, such as bending and prying with blade, may cause the blade to bend or fracture and could result in damage to tissue in the surgical site and/or loss of tactile control.
- If using a device with a safety lock, such as a MicroDriver or Universal Handswitch, always place that device in the SAFE position when not in use. IMPORTANT: Be aware that the TPS footswitch will override the Universal Handswitch SAFE setting.
- Always use the appropriate accessory combination with a handpiece. Contact your Stryker sales representative for a complete list of accessories. Failure to comply may result in patient and/or operating room staff injury.
- Please note the handpiece starts with rapid acceleration when the footswitch or handswitch is activated.
- During initial use of your TPS handpieces, monitor the heat response in relation to the type of surgical procedure being performed. Frequently check the distal tip and body until you are familiar with its temperature rise characteristics. Failure to pay close attention to handpiece temperature may cause burn injury to patient.
- Operating a handpiece in the Window Jog mode may cause the handpiece to overheat. If a handpiece overheats, the console automatically turns off the handpiece. (The alarm does not sound in this event.) Carefully monitor the operating time to prevent the handpiece from overheating. Failure to comply may cause injury to the patient and/or the operating room staff.

System Overview

The Stryker Total Performance System is intended for use in the cutting, drilling, decorticating, and smoothing of bone and other bone related tissue in a variety of surgical procedures. It is also used for the placement or cutting of screws, wires, pins, and other fixation devices as it can be used to cut metal.

TPS console powers multiple handpieces while allowing the user to program a number of customized settings.

Symbol Definition

Power ON

Power OFF

Footswitch Connector

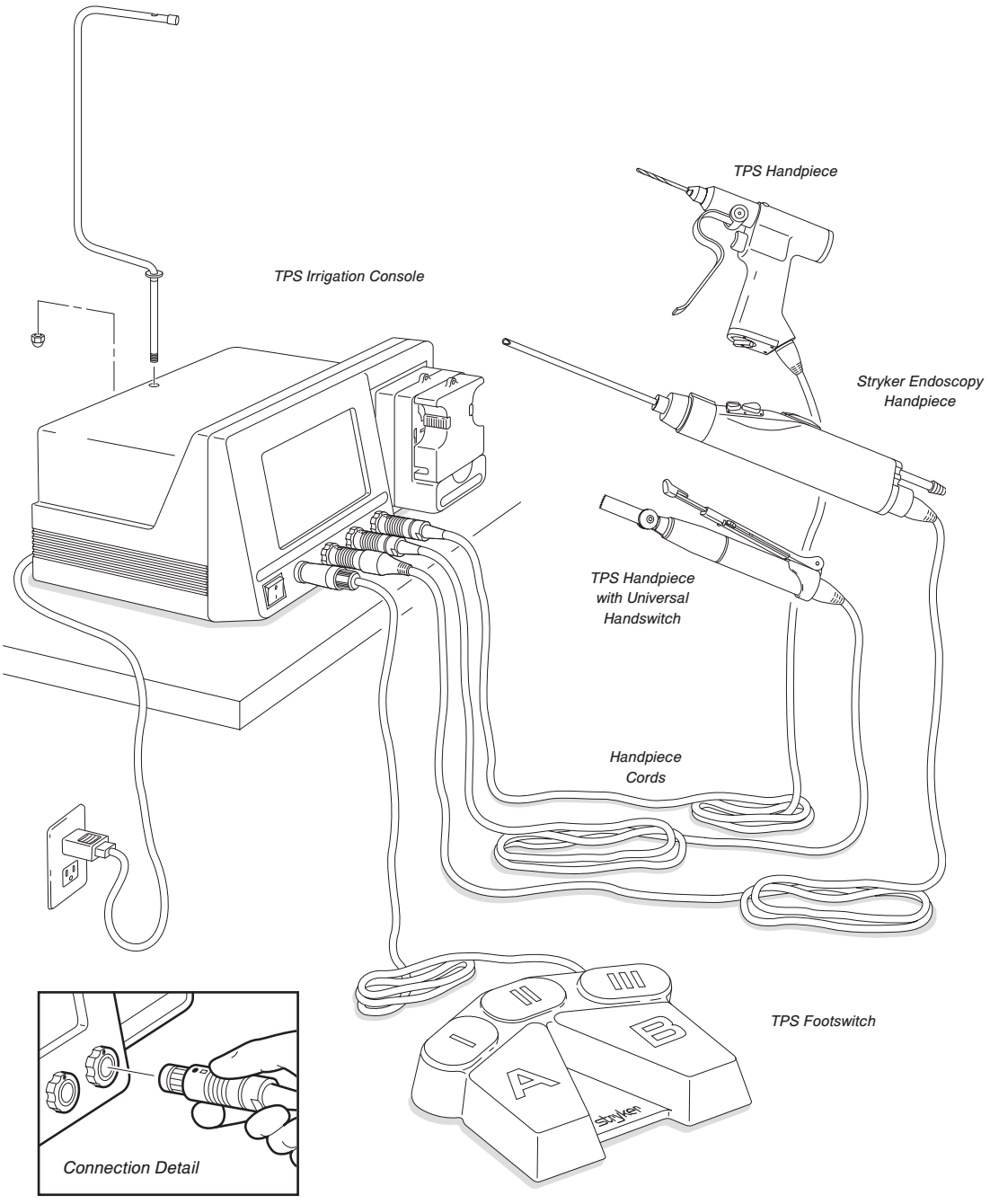
ENDO
Endoscopy Handpiece Port

TPS1
TPS Handpiece Port 1

TPS2
TPS Handpiece Port 2

Type B Applied Part

Type BF Applied Part



Operating Instructions

WARNINGS:

- Before using this system read and understand the information in this manual and the instructions supplied with each TPS component and Stryker Endoscopy handpieces. Pay close attention to the User/Patient Safety Information.
- Familiarization with the Total Performance System prior to use is important. If you have any questions, contact your Stryker Instruments representative or Stryker Customer Service at 1-800-253-3210.
- Prior to use, system components should be operated and inspected for any damage. DO NOT use if damage is apparent.

Connecting the Equipment

This is a system overview. For specific instructions on each TPS component, refer to the information supplied with the component.

1. **Place your console on a sturdy, flat surface near a hospital grade outlet.**
2. **Plug the console's power cord into the recessed power socket on the back of the console.**
3. **Plug the other end of the power cord into a hospital-grade wall outlet.**
4. **Turn on the console. The on/off switch is located on the front of the console.**

   NOTE: As you set up the system, the console's screen will change to indicate the various components as they are plugged in.
5. **If using a Footswitch, plug the footswitch cable into the console port marked FOOTSWITCH.** Align orientation marks and gently push connectors together.

CAUTION: All TPS Cords have push/pull connectors. Do not thread or twist for insertion or removal.

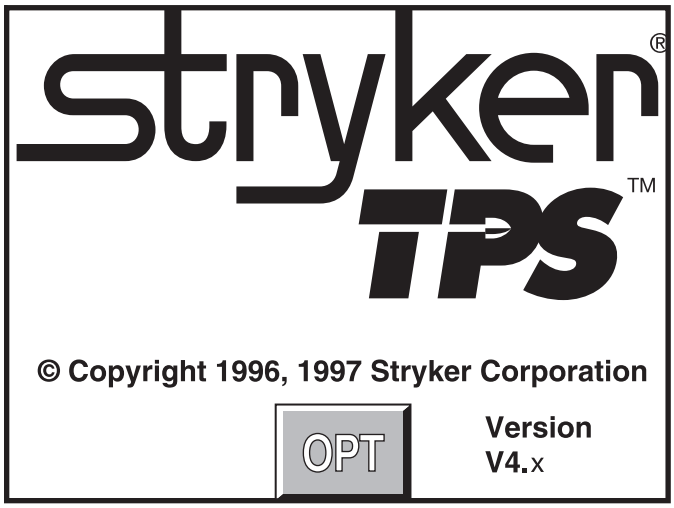
6. **Plug the handpiece cord(s) into the console port(s) identified for the handpiece.** Align connector orientation marks and gently push connectors together.
   NOTE: Ports marked TPS1 and TPS2 are for Stryker TPS handpieces only.
   The port marked ENDO is intended for the following list of Stryker Endoscopy handpieces: SE5 Handpiece REF 272-704-100, SE5 Hand-controlled REF 272-704; QuadraCut Shaver REF 275-701; QuadraCut Bone Plug REF 275-705; and QuadraCut small Joint REF 275-601.
   NOTE: If using a TPS Universal Handswitch, attach it to the handpiece before you plug the cord into the handpiece.
7. **Plug the other end of the handpiece cord(s) into the handpiece(s).**
8. **Attach cutting accessories to handpieces.** Instructions supplied with each handpiece or attachment provide details for cutting accessory assembly.

   WARNING: Use only Stryker approved cutting accessories.
9. **If using an Irrigation Console REF 5100-50, assemble Irrigation Pole REF 5100-50-28 to the console as shown.** Hang irrigation bag from pole. Install irrigation cassette into the pump. Attach irrigation clips to handpieces and connect tubing.
10. Power the system and test the devices to ensure they are performing properly prior to surgery.

WARNINGS:

- Portable and mobile RF communications equipment can affect the TPS Console.
- The TPS Console should not be placed adjacent to or stacked with other equipment. If adjacent to or stacked, the equipment must be observed to verify normal operation.

The Control Screen



TPS Start-Up Screen

This display appears on the screen every time the console is turned on.

This display remains on the screen until a cord is plugged into one of the TPS handpiece ports or the OPT button is depressed.

If a handpiece cord is plugged into a handpiece port when the console is turned on, this display shows momentarily before changing to either a no handpiece detected screen or to the screen of the selected handpiece.

This example shows that no handpiece is attached to the cord plugged into the TPS2 port.

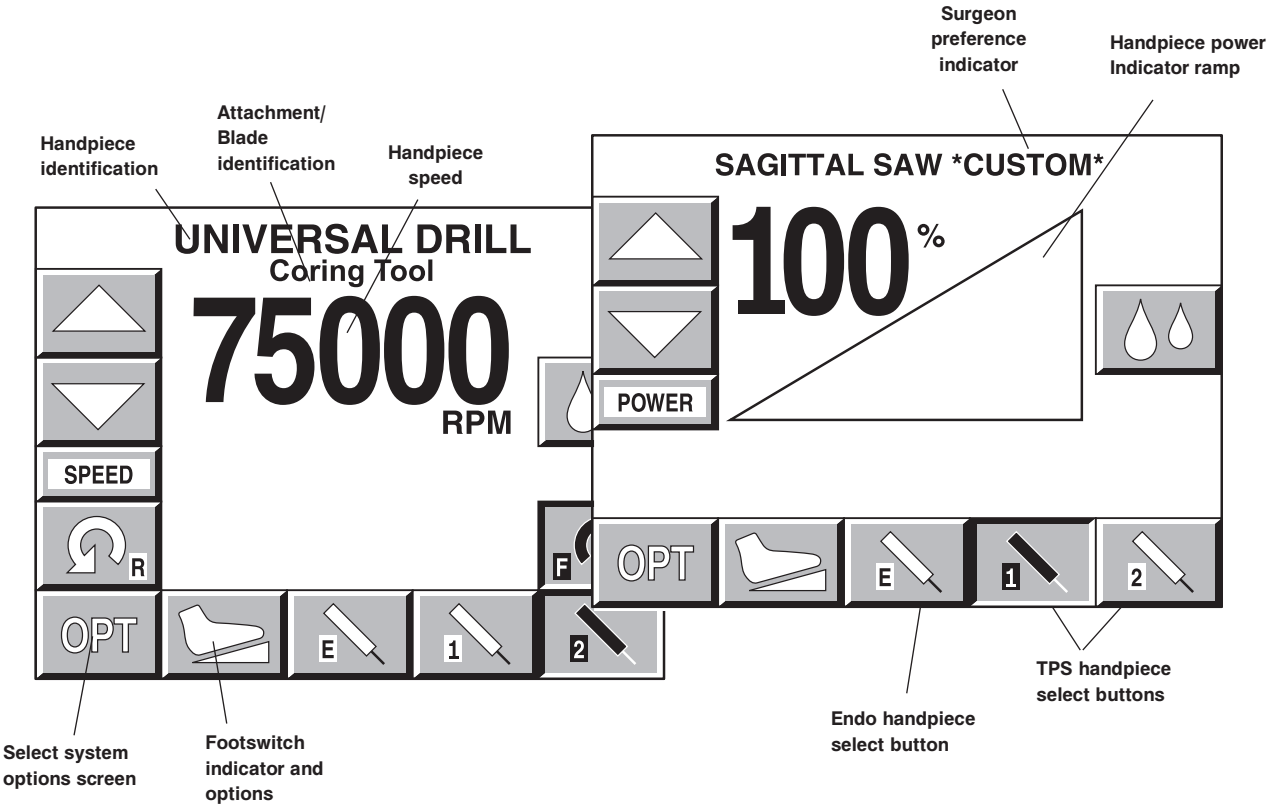
No Handpiece Detected Screen

This image indicates that no handpiece is attached to the cord plugged into the selected port. The screen will change to the handpiece screen when the missing handpiece is connected to the cord.

NOTE: This screen will also appear if the console is unable to recognize the handpiece. This could be caused by a handpiece that is not compatible with the TPS console, or a faulty or damaged handpiece or cord.

Functions of the Control Screen

The TPS console allows the user to select functions and settings such as handpiece selection, speed, and direction. Designed to be easy to use and understand, the touch sensitive **control screen** allows you to set the system controls with the touch of a finger. Interactive **icons** on the control panel represent system components and functions. The control screen also provides important monitoring information for the selected handpiece.



Elements of the Control Screen

Control screen visually presents options which can be set for the selected handpiece.

Icons represent elements of your TPS system. Icons are functional buttons. Each function may be selected by pressing the screen where the button is displayed. When you touch an icon, the icon appears to be pressed down and the graphic symbol highlights to indicate that it is activated. (See Icon Definition).

NOTE: An audible signal indicates interface with icons.

NOTE: Buttons such as the adjust arrows or OPT button which are temporary toggles or adjustment buttons only highlight while depressed.

NOTE: Buttons with a white background are toggle buttons.

NOTE: Options vary among different handpieces. The console will only display the options available for a given handpiece.

Handpiece identification displays the name of the active handpiece. NOTE: Handpieces can be plugged into each of the console's handpiece ports, but only one can be selected at a time.

NOTE: When *CUSTOM* is displayed at the top of the screen, the console's default settings are selected from Surgeon Preferences. The console is able to capture the preferred settings for several different users. When this feature is activated, the preferred settings act as default settings. See Surgeon Preference for further details.

Handpiece speed information displays the default speed for each handpiece until you reset speed settings.
While the handpiece is running, the display shows the actual handpiece speed. If the handpiece is not running the default or selected speed is displayed.

NOTE: Incremental information displayed on the control screen is accurate within +/-1%.

Select Your System Settings

NOTE: When the console is turned on, its default setting is factory default unless a Surgeon Preference setting is selected as the start up default. See Surgeon Preference for further details.

1. Handpiece select buttons enable you to activate the handpiece plugged into one of the three ports on the front of the console. **To display the control screen for the handpiece plugged into the TPS1 port, touch the corresponding handpiece select icon.** The icon highlights and appears pressed down.

   NOTE: Selecting a handpiece icon activates the corresponding handpiece and displays its specific control screen.

2. **Change the maximum handpiece speed.** Press the adjustment arrows to change the handpiece speed setting incrementally until the desired speed is reached.

   • Saws - The set point is displayed as a percentage of maximum power and vertical line on the speed ramp. During handpiece operation, the percentage reading and speed ramp displays the power level.

   • Rotary handpieces - The speed set point is displayed. During handpiece operation, the current speed is displayed.

3. **Select various settings as desired.** Refer to the control screens on the following pages for details for each handpiece.

4. **Select the OPT icon to access the MAIN OPTION screen.** This screen allows access to general console and user settings as well as direct access to each handpiece option screen.

   NOTE: The screen returns to the active handpiece adjustments screen when the handpiece name is touched.

5. **Touch the EXIT icon to return to the active handpiece control screen.**

Standard Features

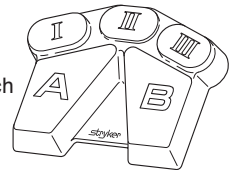
Main Option Icon

The option icon appears on all handpiece screens and allows access to the MAIN OPTION screen. See MAIN OPTION SCREEN for further details.

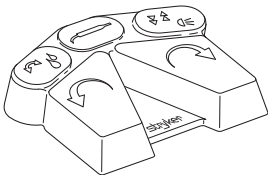
Footswitch Icon

The footswitch icon only appears when a footswitch is plugged into the console.

If using a footswitch with these graphics, pedal functions can be reprogrammed. See Footswitch Adjustments and Footswitch Button Mapping.



A footswitch with these graphics cannot be reprogrammed.



Handpiece Irrigation

Irrigation functions pertain only to Irrigation Console REF 5100-50.

Press the icon to start irrigation flow while the handpiece is running.

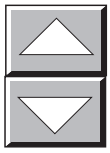
If irrigation is desired while the handpiece is stopped, press and hold the icon until the pump is activated. The pump can be turned off by touching the icon again.

Irrigation flow rate can be adjusted from the HANDPIECE screen or the HANDPIECE ADJUSTMENTS screen.

From the HANDPIECE screen, toggle the SPEED icon to WATER before using the arrows to adjust flow rate.

-OR-

From the HANDPIECE ADJUSTMENTS screen, select the WATER icon and use the arrows to adjust flow rate. Flow rate diminishes as the setting approaches zero.



NOTE: Flow rate may vary among handpiece models.

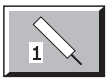
The pump can also be turned on and off with the footswitch.

Quick Reference Guide
Icon Definition

Handpiece Select

This type of icon appears when a cord (without a handpiece) is plugged into the corresponding Endo, TPS1 or TPS2 port.

It appears depressed when selected.



The handpiece graphic appears when a handpiece is attached to the corresponding cord.

The handpiece graphic highlights and the icon appears depressed when selected.

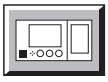
System Options

Options: Gives access to handpiece adjustments, system information, console adjustments and user preference.

Handpiece option: Accesses corresponding handpiece adjustment screens.

Exit: Returns to previous screen.

Information: Displays system information screen.

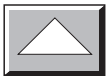


Console: Gives access to console adjustment screen.

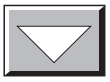
Allows access to the surgeon preference screen.

Footswitch Icon: Appears when a footswitch is connected to the console. Also gives access to footswitch adjustments screen.

Adjustment Arrows: Use in conjunction with other options to set handpiece speed or power, braking, acceleration, irrigation flow, screen contrast etc.



Increase



Decrease

Direction Arrows: Sets handpiece mode.

Forward (clockwise)

Reverse (counterclockwise)

Oscillate

Irrigation: Activates or deactivates handpiece irrigation.

High: Enables handpiece to operate in a high speed mode.

Low: Enables handpiece to operate in a low speed mode.

Toggle Buttons

NOTE: For easy identification, only toggle buttons have a white background.

Speed: Use with the increase and decrease icons to adjust rotary handpiece speed.

Water: Use with the increase and decrease icons to adjust irrigation flow.

Power: Use with the increase and decrease icons to adjust saw power.

Variable: Handpiece speed responds to varying degrees of pressure on the footswitch or handswitch.

Nonvariable: Handpiece operates at constant set-point speed/power level.

One touch: Handpiece is activated by one touch of a trigger device and continues to run when the trigger device is released. Handpiece is deactivated by touching <u>any</u> trigger device. In this mode, the handpiece operates at constant set-point speed/power level.

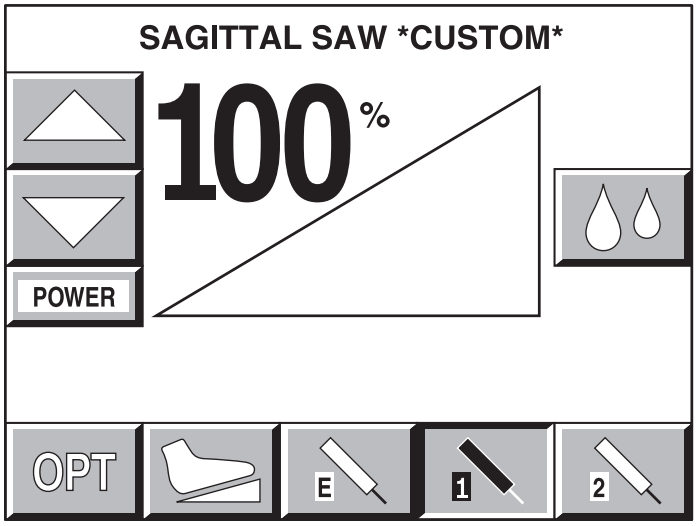
Advanced: - Accesses the advanced footswitch mapping screen.

Button: Access button mapping screen.

Return to full screen: Return from Big to full handpiece screen.

NOTE: TPS Console REF 5100-1 does not display options related to handpiece irrigation.

Saw Handpiece Screen



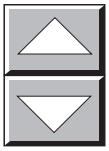
This screen appears when a TPS saw is selected at the TPS1 port with the maximum power set at 100%.

ENDO, TPS2 and the footswitch icons indicate other instruments are plugged into the console.

TPS Oscillating and Sagittal Saws

POWER/WATER ADJUSTMENT

The power icon functions as a toggle switch for power and water settings.



Power and irrigation adjustments are made using the adjustment arrows.

As the power setting is reduced from 100%, a vertical bar displays to correspond to the lower selected maximum power.

The irrigation setting is not displayed on this screen. However, it can be seen on the Handpiece Adjustments screen.

METHOD OF OPERATION

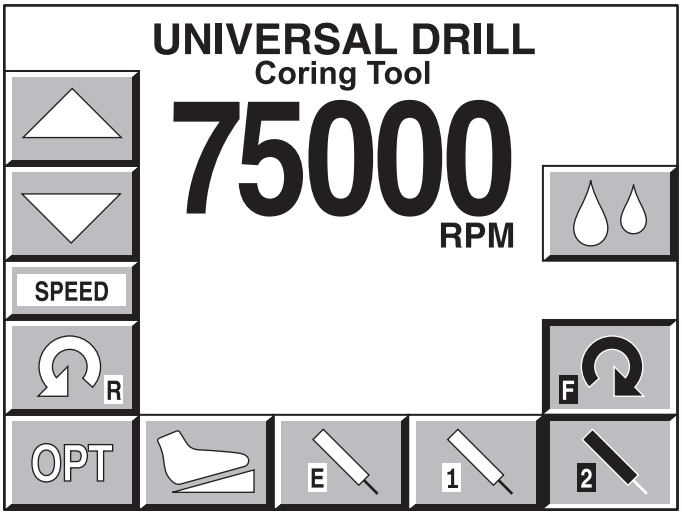
Saws can be operated with the TPS Universal Handswitch or TPS Footswitch.

Handswitch Handpiece selection can be made by depressing the handswitch once. The handpiece select icon changes to indicate the active handpiece. Depress the handswitch again to run the handpiece.

Handpiece runs from start-up to the maximum selected speed.

Footswitch Handpiece runs from start-up to the maximum selected speed with either the forward or reverse pedal.

Rotary Handpiece Screen



This screen appears when a TPS rotary handpiece is selected. The TPS Universal Drill is plugged into the TPS2 port and the speed is set at 75,000 RPM.

ENDO, TPS1 and the footswitch icons indicate that other instruments are plugged into the console.

TPS Universal and Micro Drills

METHOD OF OPERATION
The Universal Drill can be operated with the TPS Universal Handswitch or TPS Footswitch.

Handswitch Handpiece selection can be made by depressing the handswitch once. The handpiece select icon changes to indicate the active handpiece. Depress the handswitch again to run the handpiece.

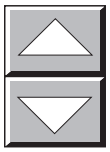
Handpiece runs from start-up to the maximum selected speed. Speed and cutting direction corresponds to what is selected on the screen.

Footswitch Handpiece runs from start-up to the maximum selected speed.

Handpiece direction is controlled by selecting the forward or reverse pedals. The direction icon on the screen changes when the corresponding footswitch pedal is depressed.

SPEED/WATER ADJUSTMENT

The speed icon functions as a toggle switch for speed and water settings.



Speed and irrigation adjustments are made using the adjustment arrows.

DIRECTION OPTIONS

FORWARD Clockwise

REVERSE Counterclockwise

OSCILLATE

TPS MicroDriver and Universal Driver

METHOD OF OPERATION
The TPS MicroDriver can be operated with its built-in trigger and rotary control switch or with the TPS Footswitch.
NOTE: The handpiece will not run when the rotary switch is in the SAFE position.

Trigger The built-in speed control trigger(s) runs the handpiece from start-up to the maximum selected speed.

MicroDriver only: Select cutting direction with the rotary switch on the handpiece. Direction icon will highlight to match the rotary switch position.

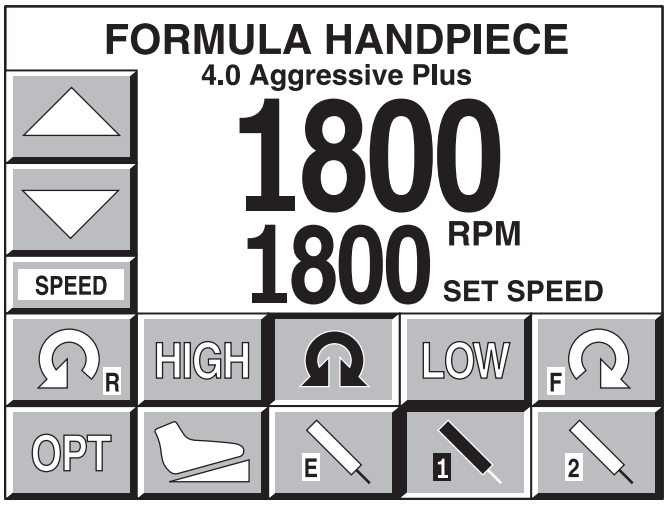
Universal Driver only: Select cutting direction by depressing either the forward trigger or the reverse trigger. Squeezing both triggers simultaneously runs the handpiece in the oscillate mode. The oscillate icon will become highlighted.

Footswitch Handpiece runs from start-up to the maximum selected speed.

The direction icon on the screen changes when the corresponding footswitch pedal is depressed.

Footswitch operation overrides handpiece settings. *Example:* If the footswitch reverse pedal is depressed while the handpiece rotary switch is set in forward, the handpiece operates in the reverse direction and the reverse icon highlights. However, after the pedal is released, the direction icon will revert to the direction set on the rotary switch.

The Stryker Endoscopy and Leibinger Handpiece Screen



This screen appears when a Formula handpiece with cutter recognition is selected. The oscillate mode is selected and Set Speed is set at 1,800 RPM.

TPS1, TPS2 and the footswitch icons indicate that other instruments are plugged into the console.

The Stryker Leibinger Hummer4 REF 5290-601-100 and Stryker Endoscopy Formula REF 375-701-500 provide cutter recognition capabilities.

> ⚠ WARNING: Read and understand the Stryker Endoscopy handpiece instructions.
>
> **If instructions were not supplied with your handpiece, refer to the appropriate Stryker Endoscopy Operating and Maintenance Manual listed below.**
>
> | **Handpiece** | **Manual** |
> |---|---|
> | 272-704 | 1000-400-120 |
> | 275-701 | 1000-400-034 |
> | 275-705 | 1000-400-034 |
> | 275-601 | 1000-400-034 |
> | 290-601 | 1000-400-288 |
>
> **IMPORTANT INFORMATION**
> The hand-controlled Endo Shaver can be controlled by the footswitch or by the hand-control buttons built into the handpiece.
>
> The handpieces listed here do not have cutter recognition capabilities.

This screen displays the cutter nomenclature only if the handpiece and cutter being used contain cutter recognition capabilities.

Depress the mode icon and set the maximum speed using the adjustment arrows. Speed settings are individually selected for each mode.

Default speed settings and incremental steps are specific to each handpiece.

MODES

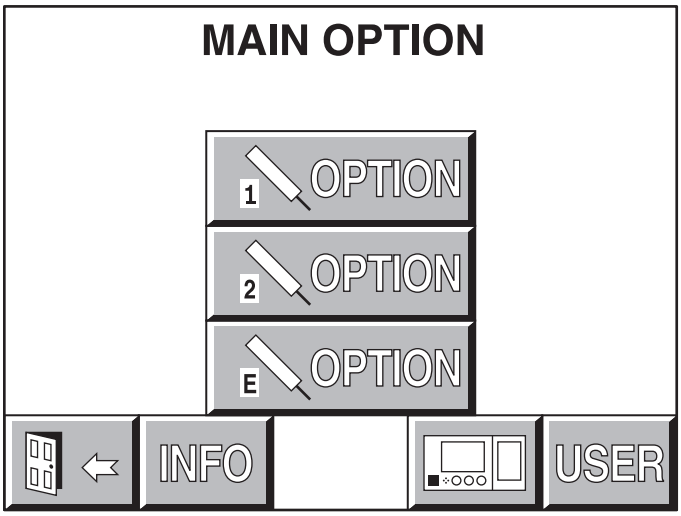
Operation in high speed mode.

Operation in oscillate mode.

Operation in low speed mode.

When a cutting accessory with cutter recognition capabilities is installed, the system may override selected speed settings within each mode to more appropriate speed settings for that particular cutting accessory.

OPT Main Option Screen



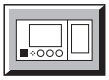
Select the OPT icon to access the MAIN OPTION screen. This screen allows direct access to the handpieces attached to the console, console and user settings, and system information.

OPTION 1, 2, and E icons appear only when handpieces are plugged into the corresponding console ports. A handpiece must be plugged in to program its settings.

To go to the HANDPIECE ADJUSTMENT screen, touch the option button that corresponds to the desired handpiece. Refer to HANDPIECE ADJUSTMENT.

The MAIN OPTION screen also gives DIRECT access to:

Refer to SURGEON PREFERENCE.

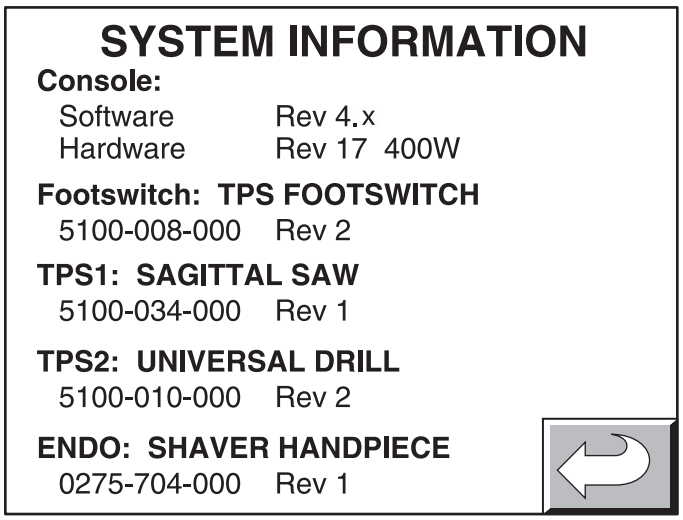


Refer to CONSOLE ADJUSTMENT.

Refer to SYSTEM INFORMATION.

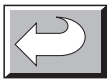
EXIT: Return to handpiece screen.

System Information Screen



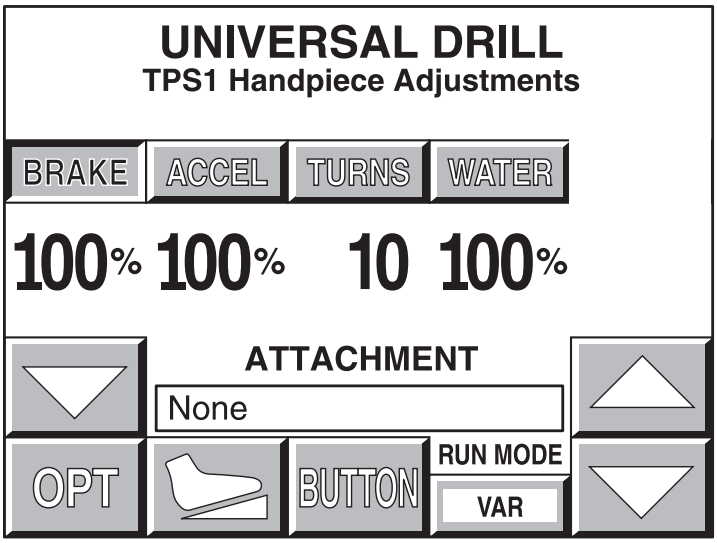
Selecting the INFO icon from the MAIN OPTION menu displays the part numbers and revision levels of the configured system components.

This information is used as a diagnostic aid only.



Return to the MAIN OPTION screen.

Handpiece Adjustment Screen



Select a Handpiece Option icon from the MAIN OPTION screen to access this screen.

NOTE: For quick access to this screen, touch the handpiece title displayed at the top of any handpiece screen. And return to the handpiece screen by touching the handpiece title displayed on this screen.

Depending on the type of handpiece, one or more of the following options will be available.

Select BRAKE, ACCEL, TURNS or WATER then press the arrow icons to change the setting.

Brake: At 100%, the handpiece stops abruptly. Deceleration slows as the setting nears zero.

Accelerate: At 100%, handpiece speed accelerates quickly. Acceleration slows as the setting approaches zero.

Turns: Use to set the number of turns per direction when running a handpiece in the oscillate mode. The minimum setting will set the oscillate function to operate in a TIME-BASED mode where the number of turns are based on the speed of the handpiece.

Water: At 100%, irrigation volume is greatest. Volume decreases as the setting approaches zero.

ATTACHMENT: Use the arrow icon on the left to scroll through the list of attachments. Select the attachment that is assembled to the handpiece by stopping on it.

Selecting the proper attachment will optimize the performance of the handpiece for the attachment and display the appropriate speed scale on the handpiece screen.

RUN MODE: Use the RUN MODE toggle button to scroll through the options and stop on the desired setting.

Variable: Handpiece speed responds to the degree of pressure applied to the handswitch.

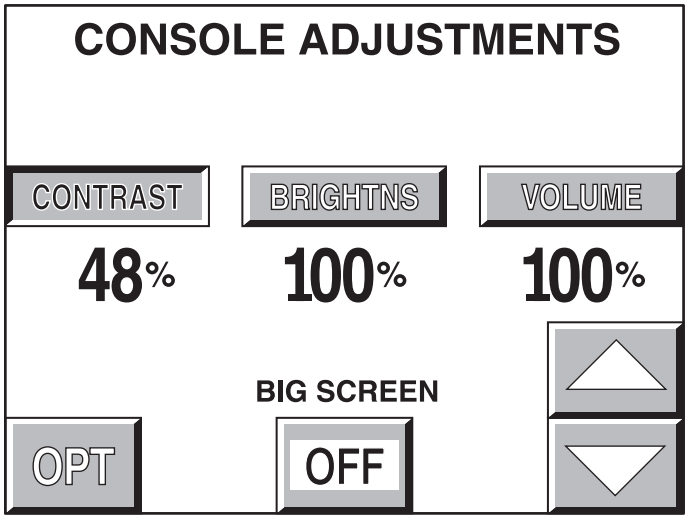
Nonvariable: Handpiece speed runs at the maximum setting only. Varying pressure on the handswitch does not vary the handpiece speed.

One touch: Toggle the handpiece on and off with a single touch of a trigger device. The trigger device can be the handswitch or handpiece trigger buttons.

BUTTON: See Handpiece Button Mapping.

FOOTSWITCH: Activates FOOTSWITCH ADJUSTMENTS. See Footswitch Adjustments.

Console Adjustment Screen



Select the CONSOLE ADJUSTMENTS icon from the MAIN OPTION screen to access this screen.

Select CONTRAST, BRIGHTNESS or VOLUME then press the arrow icons to change the setting.

Contrast: Screen contrast lightens at higher settings. The chosen setting remains until reset.

Brightness: Screen brightness intensifies at higher settings.

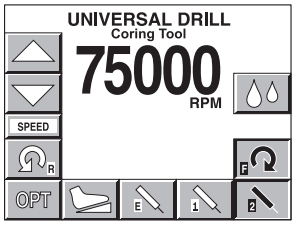
Volume: The audible signal is louder at higher settings.

Use the BIG SCREEN toggle button to select one of the following options.

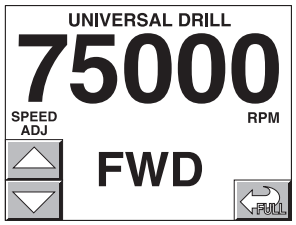
Automatic: A big screen is displayed while the handpiece is running and automatically returns to the full screen when handpiece stops.

On: The big screen is continuously displayed. It can be temporarily switched back to the full screen by touching the Full Screen icon which appears in the lower right corner of each handpiece screen. See example of screens below.

Off: The big screen option is turned off. Only a full screen is displayed.

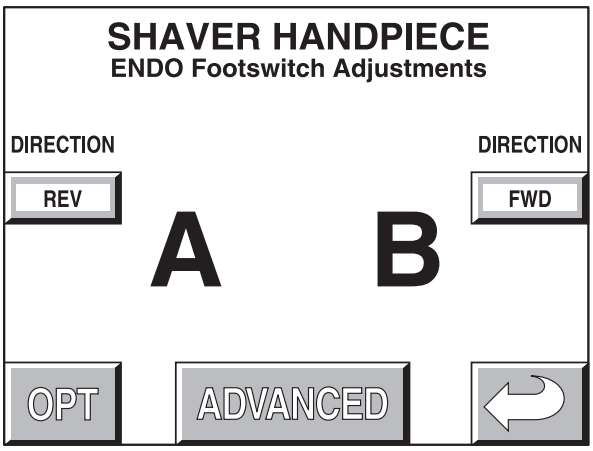


Example of full screen.



Example of big screen.

Footswitch Adjustment Screen



This screen appears only when using a TPS Footswitch that is Revision 3 or newer. See Standard Features.

NOTE: The Footswitch revision is displayed on the SYSTEM INFORMATION screen.

Access this screen by selecting the Footswitch icon on the HANDPIECE CONTROL SCREEN or HANDPIECE ADJUSTMENTS screen.

NOTE: These footswitch settings function only for the handpiece for which they were selected. The handpiece is identified at the top of the screen.

From this screen, the default functions of footswitch pads A and B can be reprogrammed to accommodate the surgeon's preferences. The left and right toggle icons correspond respectively to footswitch pads A and B. Press each icon to scroll through the following function options and stop on the desired setting.

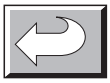
Off: Pedal is turned off.

Default: Footswitch defaults to the settings selected on the handpiece screen.

Forward: Pedal setting default is overridden. Pedal will provide handpiece rotation in the forward (clockwise) direction.

Reverse: Pedal setting default is overridden. Pedal will provide handpiece rotation in the reverse (counterclockwise) direction.

Advanced: Use to access the Footswitch Button Mapping screen. It will allow you to reprogram all the footswitch pedals.



Return: Return to the previous screen.

ADVANCED Footswitch Button Mapping Screen

Access this screen by selecting the ADVANCED icon on the FOOTSWITCH ADJUSTMENTS screen. The default functions of each footswitch pedal and button can be reprogrammed to accommodate the surgeon's preferences.

Depending on the type of handpiece displayed at the top of the screen, one or more of the following options will be available on this screen.

The DIRECTION, OP MODE, and RUN MODE icons correspond respectively to the two largest footswitch pedals. Press each icon to scroll through the following function options. And stop on the desired function setting.

DIRECTION

OFF — Pedal is turned off.

DEFAULT — Footswitch defaults to the settings selected on the handpiece screen.

FWD — **Forward:** Pedal setting default is overridden. Pedal will provide handpiece rotation in the forward (clockwise) direction.

REV — **Reverse:** Pedal setting default is overridden. Pedal will provide handpiece rotation in the reverse (counterclockwise) direction.

OP MODE

DEFAULT — Footswitch defaults to the settings selected on the handpiece screen.

HIGH — Handpiece operates in the high speed range.

LOW — Handpiece operates in the low speed range.

OSC — Handpiece operates in oscillate mode.

RUN MODE

DEFAULT — Footswitch defaults to the settings selected on the handpiece adjust screen.

VAR — **Variable:** Variable speed control. Speed responds to varying degrees of pressure on the footswitch.

NON VAR — **Nonvariable:** Handpiece operates at a constant speed level determined by the maximum speed selected from the handpiece screen.

1 TOUCH — **One touch:** The one touch function is similar to an on/off toggle. Tap the footswitch to operate the handpiece at the maximum speed selected from the handpiece screen. Tap any trigger device again to stop operation.

BUTTON FUNCTION

The **I, II,** and **III** icons correspond to the three small pads across the top of the footswitch.

Button Function displays the active function of the corresponding button.

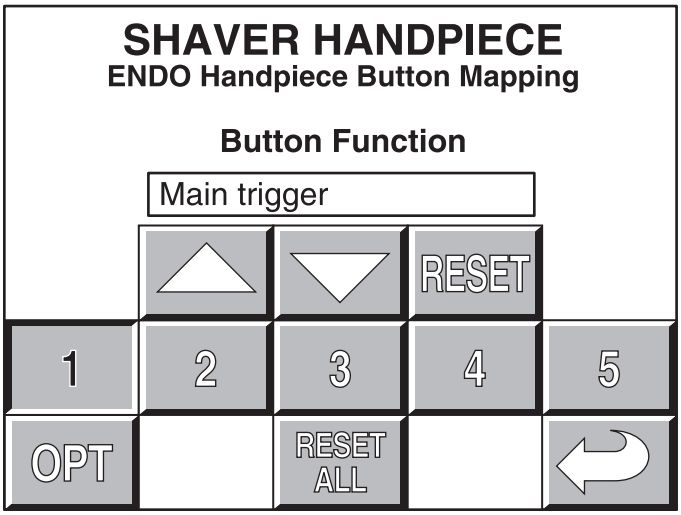
Use the arrow icons to scroll through the functions and stop on the desired setting.

See Button Functions listed on next page.

RESET ALL — **Reset all:** Press to return all pedals and buttons back to their default setting.

RESET — **Reset:** Press to return the selected footswitch button back to its default setting.

BUTTON Handpiece Button Mapping Screen



Access this screen from the Handpiece Adjustment screen. Use it to change handpiece button functions.

Depending on the features of the handpiece, as many as five buttons can be reprogrammed. Identify corresponding button numbers by pressing the buttons on the handpiece. When the handpiece button is selected, the corresponding function is displayed on the screen. Use the arrow icons to scroll through the function options. Stop on the desired option. See the list below for a description of the options.

NOTE: Available options are handpiece specific.

BUTTON FUNCTIONS

RESET **Reset:** Select to return a single button to its default function.

RESET ALL **Reset all:** Select to return all buttons to their default functions.

Return: Return to previous screen.

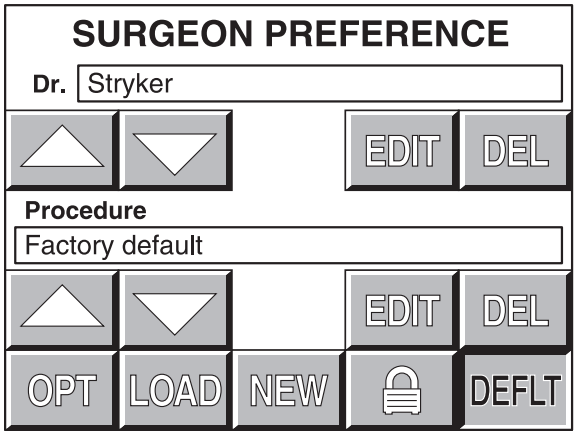
Button Functions List

Button Function	Description
Main trigger	Starts handpiece in default direction and mode.
FWD trigger	Starts handpiece in forward direction in default mode.
REV trigger	Starts handpiece in reverse direction in default mode.
OSC trigger	Starts handpiece in oscillate mode.
Speed increment	Increments the set point speed.
Speed decrement	Decrements the set point speed.
Water increment	Increments the pump flow set point.
Water decrement	Decrements the pump flow set point.
Water on/off	Toggles the pump on/off button. If pressed and held, the pump can be turned on without running the handpiece. Once started, the pump can be stopped by pressing the button again or by starting the handpiece.

Button Function	Description
Osc <> **High/low**	Toggles the run mode between oscillate and high or low.
High <> **Low**	Toggles the run mode between high and low.
Forward <> **Reverse**	Toggles the running direction.
Change port	Changes the active handpiece port.
Change attachment	Scrolls through the attachment list for the selected handpiece.
Pump flush	Turns the pump on at the flush rate. Once started the pump can be stopped by pressing the button again or by starting the handpiece.
Make port active	Makes the selected handpiece active.
Window jog	Slowly rotates the inner cutter for positioning within the outer cutter's window.

WARNING: Operating a handpiece in the Window Jog mode may cause the handpiece to overheat. If a handpiece overheats, the console automatically turns off the handpiece. (The alarm does not sound in this event.) Carefully monitor the operating time to prevent the handpiece from overheating. Failure to comply may cause injury to the patient and/or the operating room staff.

USER Surgeon Preference Screen



Access the SURGEON PREFERENCE screen from the MAIN OPTIONS screen.

The console is able to capture and store the preferred settings of different surgeon's.

There are three options:
- Factory default settings
- Settings saved by a previous surgeon
- Collection and storage of new settings

Using factory settings

1. Use the arrows to obtain "Stryker" and "Factory Default."

NOTE: The EDIT, DELETE and padlock icons do not function while factory default settings are selected.

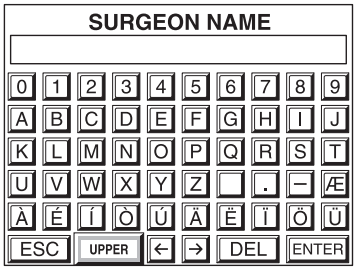
Using the settings saved by a previous user

1. Use the arrows to select the surgeon and procedure.
2. Select LOAD. Screen returns to the MAIN OPTION screen.
3. Proceed with surgery.

Collect and store preferred settings

1. Select NEW. The editor screen will appear with the selected surgeon's name.
2. To create a new procedure under this surgeons name, select ENTER. Or if you wish to collect and store settings under a new surgeon name, use the key pad to delete (DEL) the existing name then key-in the new name. Upon completion, select ENTER.
3. Use the key pad to enter the procedure name.
4. Upon completion, select ENTER. The screen returns to the SURGEON PREFERENCE screen.
5. Toggle padlock icon so that the padlock appears open.
6. Select LOAD.
7. Configure system settings.
8. Upon completion, return to the SURGEON PREFERENCE screen.
9. Toggle the padlock icon so that the padlock appears locked.

NOTE: If the padlock icon remains in the unlocked position, the selected settings will be continuously updated with current settings.



This is the key pad screen used to enter the doctor's name and name of procedure.

Padlock opened to gather preferences.

Padlock closed to store preferences.

Select to add a surgeon name.

Select to change the doctor name and/or procedure.

NOTE: Toggle the UPPER/LOWERCASE pad on the editor screen to select letter case.

Delete: Select to delete the currently displayed file.

Select and use with the open padlock to gather (load) new preference settings.

Default: Using the arrows, scroll the SURGEON PREFERENCE screen to the desired surgeon and procedure settings before activating DEFLT. This selection becomes the default power on setting for the system until a different selection is made.

Messages

Message	If you select OK to this question:
Delete all the surgeon's procedures?	The surgeon ID and all procedures will be deleted.
Change the name of all the surgeon's procedures?	Procedures listed under the surgeon will be moved under the current surgeon's name.

Identical record found.

Maximum number of records exceeded. Please delete inactive records.

Initializing console hardware. Please wait.

Handpiece has reached recommended service interval. Please return for service at earliest convenience.

Handpiece does not support the selected preference. Default handpiece setting will be used.

Handpiece temperature has exceeded its nominal operating range and may cause burning.

Handpiece temperature has exceeded its operating range. Allow to cool before restarting.

Procedure name unspecified.

Ensure handpiece speed does not exceed specified attachment limitations. Failure to do so may result in user and/or patient injury.

Cutter/bur is not compatible with the current handpiece.

Cutter/bur has exceeded its life. Please replace with a new cutter/bur.

Error Messages

Message		Action to Take
Error 001.	**Console hardware fault detected.**	Return console to Stryker for repair.
Error 002.	**Console hardware fault detected. Contact your Stryker service representative.**	Turn unit off and on again. If problem persists, return console to Stryker for repair.
Error 003.	**Console hardware fault detected. Contact your Stryker service representative.**	Turn console off and on again. If problem persists, return console to Stryker for repair.
Error 004.	**Footswitch fault detected, right pedal will be disabled. Contact your Stryker service representative.**	Unplug Footswitch from console and plug in again. If problem persists, return footswitch to Stryker for repair.
Error 005.	**Footswitch fault detected, left pedal will be disabled. Contact your Stryker service representative.**	Unplug Footswitch from console and plug in again. If problem persists return footswitch to Stryker for repair.
Error 006.	**Footswitch unreadable. Contact your Stryker service representative.**	Unplug Footswitch from console and plug in again. If problem persists, return footswitch to Stryker for repair.
Error 007.	**Handpiece fault detected, handpiece triggers will be disabled. Contact your Stryker service representative.**	Unplug cord from handpiece and plug in again. If problem persists, return handpiece to Stryker for repair.
Error 008.	**Handpiece unreadable. Contact your Stryker service representative.**	Unplug handpiece from console and plug in again. If problem persists, return handpiece Stryker for repair.
Error 009.	**Handpiece requires additional console hardware. Contact your Stryker service representative.**	Call your Stryker Instruments sales representative.
Error 010	**Handpiece requires additional console hardware. Contact your Stryker service representative.**	Call your Stryker Instruments sales representative.
Error 011	**Handpiece requires additional console hardware. Contact your Stryker service representative.**	Call your Stryker Instruments sales representative.
Error 012	**Cutting accessory requires additional console hardware.**	See the instructions supplied with the cutting accessory.

The Total Performance System is not field repairable. In case of operating difficulties, Stryker products must be returned for maintenance or repair.

Specifications

Models: 5100-1 & 5100-1A TPS Console
5100-50 & 5100-50A TPS Irrigation Console

Size: 11.8 in. [299 mm] width
7.0 in. [179 mm] height
9.0 in. [229 mm] depth
12.2 in. [310 mm] depth (units with irrigation pump)

Weight: 9 lbs. [4.1 Kg]
14.1 lbs. [6.4 Kg] (units with irrigation pump)

Electrical: 100-120VAC, 50-60Hz, 6.0A
220-240VAC, 50Hz, 3.0A

Approval:

C US

CSA International
- UL 60601-1
- CAN/CSA-C22.2 No. 601.1 M90
- IEC 60601-1

Class I

PORT	TYPE	SYMBOL
Endo	B	
TPS1	BF	
TPS2	BF	

IPX0 Ordinary Equipment

Protective Earth Ground

Duty Cycle: **Continuous operation with intermittent loading**
Refer to cycle times defined in the TPS handpiece instructions.

Handling your console and equipment

- When setting up your console, place on a sturdy, flat surface, and carefully follow all setup instructions.
- When connecting or disconnecting a cable, always hold the cable by its connector (the plug, not the cord).
- Never force a connector into a port. If the connector and port do not join with reasonable ease, they probably don't match. Make sure that the connector matches the port and that you have positioned the connector correctly in relation to the port.
- To ensure the longevity, performance, and safety of this equipment, package in original package materials when storing or transporting.

If the console experiences sporadic electrical interference:

- Turn off all electrical equipment not in use in the operating room.
- Relocate electrical equipment; increase spacial distance.
- Plug the TPS console and other operating room equipment into different outlets.

Environmental Conditions

These conditions apply to all components of the TPS system unless otherwise specified in the information supplied with that device.

Environmental Conditions:	Operation	Storage and Transportation
Temperature:	10 – 40°C	-20 – 40°C
Relative humidity:	30 – 75%	10 – 75%
Atmospheric Pressure:	700 – 1060 *hPa*	500 – 1060 *hPa*

Specifications listed are approximate and may vary slightly from unit to unit or by power supply fluctuations.

Compliance Statements

Federal Communication Commission FCC ID: Q9R-5100

This device complies with Part 15 of the FCC Rules.
Operation is subject to the following two conditions:
(1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Note that FCC regulations provide that changes or modifications not expressly approved by Stryker Instruments could void your authority to operate this equipment.

IC: 4919A-5100
The term "IC:" before the radio certification number only signifies that Industry Canada technical specifications were met.

R&TTE Declaration of Conformity (DoC)

We, **Name of company:** Stryker Instruments
Address: 4100 East Milham Avenue, Kalamazoo, Michigan 49001-6197
Authorized Representative: Jean-Yves Carentz
Contact Detail of Authorized Representative: Stryker France, ZAC Satolas Green Pusignan, Av. de Satolas Green, 69881 MEYZIEU Cedex, France

declare under our sole responsibility that the product:

Product Name: Total Performance System
Trade Name: Stryker Instruments
Type or Model: 5100-1 Console; 5100-50 Irrigation Console
Relevant supplementary information: EN/IEC 60601-1-2:2001 & EN 301-489-3:EN 300 330-2 v1.1.1

to which this declaration relates is in conformity with the *essential requirements and other relevant requirements* of the R&TTE Directive (1999/5/EC).
The product is compliant with the following standards and/or other normative documents:

SAFETY (art 3.1.a): IEC 60601-1:1995 Medical Electrical Equipment

EMC (art 3.1.b): EN 301 489-3 v1.3.1 Specific Conditions for Short-Range Devices (SRD) operating on frequencies between 9 kHz and 40 GHz.

SPECTRUM (art 3.2): EN 300 330-2 v1.1.1 Harmonized EN Covering Essential Requirements Under Article 3.2 of the R&TTE Directive

OTHER: ANSI C95.1 Safety Levels with Respect to Human Exposure to RF Electromagnetic Fields 300 kHz to 300 GHz

Supplementary information: None
Notified Body involved: TUV Rheinland Product Safety (GmbH)
Technical file held by: Stryker Instruments
Place and date of issue (of this Doc): Kalamazoo, Michigan USA, January 2004

Signed by or for the manufacturer:

Name (printed): Paul Freestone
Title: Director, Regulatory Affairs, Quality Assurance

Hereby, Stryker Instruments, declares that this Short Range Device is in compliance with the essential requirements and other relevant provisions of Directive 1999/5/EC.

Guidance and manufacturer's declaration - electromagnetic emissions		
The TPS Console is intended for use in the electromagnetic environment specified below. The customer or the user of the TPS Console should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The TPS Console uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The TPS Console is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Frequency of transmission:	13.56MHz	**Subcarrier:**	423.75kHz Manchester coding
Type of Frequency/ Characteristics of the modulation:	10% ASK	**Effective radiated power:**	50µW

Guidance and manufacturer's declaration - electromagnetic immunity			
The TPS Console is intended for use in the electromagnetic environment specified below. The customer or the user of the TPS Console should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the TPS Console, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.67\sqrt{P}$ $d=1.67\sqrt{P}$ 80 MHz to 800 MHz $d=2.33\sqrt{P}$ 800 MHz to 2.5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m) Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	
NOTE 1: At 80 MHz and 800MHz the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The TPS Console is intended for use in the electromagnetic environment specified below. The customer or the user of the TPS Console should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	95% Reduction (10ms) 60% Reduction (100ms) 30% Reduction (500ms) 95% Reduction (5s)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the TPS Console requires continued operation during power mains interruptions, it is recommended that the TPS Console be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m @ 50Hz CRT 1A/m	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Recommended separation distances between portable and mobile RF communications equipment and the TPS Console			
The TPS Console is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the TPS Console can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the TPS Console as recommended below, according to the maximum output power of the			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m **150 kHz to 80 MHz** $d = [\frac{3.5}{V_1}]\sqrt{P}$	**80 MHz to 800 MHz** $d = [\frac{3.5}{E_1}]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1: At 80 MHz and 800MHz, the separation distance for the higher frequency range applies.			

Repair and Loaner Program

This service is available in the United States only. Outside the U.S.A., contact your Stryker sales representative or your nearest subsidiary listed on the last page.

On request, Stryker Instruments will provide a loaner unit for your use while repairs are being made.
Please clean and sterilize all potentially contaminated products being sent in for repair, credit, or return of a loaner unit. The policy of Stryker Instruments is not to accept or process potentially contaminated products which do not meet this requirement.

Also, please be aware that it is unlawful to transport bio-contaminated products through interstate commerce which are not properly packaged and labeled as such.

1. **Contact Stryker Customer Service at 1-800-253-3210 to request a loaner.** Provide a name and address for shipping. Every effort will be made to send a loaner unit immediately.

2. **Send the inoperative unit to Stryker with a purchase order number of authorization for repair.** The order should explain the nature of the difficulty. Also, provide a name and address for shipping the repaired instruments.

   Return the inoperative unit to: **Stryker Instruments**
   Repair Department
   4100 E. Milham
   Kalamazoo, Michigan, 49001.

3. **The repaired unit will be shipped back and the repair invoice will follow under separate cover.** Under most conditions, repair turnaround time will be approximately 2-3 weeks.

4. **As soon as your repaired unit is returned, return the loaner to Stryker Instruments.**

Limited Warranty

For all TPS products unless otherwise specified.
In the U.S.A. only, products of Stryker Instruments are warranted to the original purchaser for a period of one year from the date of purchase, with exceptions noted below. Products are warranted to be free from defects in material and workmanship. Abnormal wear and tear or damage caused by misuse or by failure to perform normal and routine maintenance as set out in the Maintenance Manual or Operating Instructions, or as demonstrated by an authorized Stryker Instruments representative, is not covered by the warranty. Any effort at field repair or adjustment may invalidate your warranty.

The warranty extends to all purchasers and is limited to the repair or replacement of the product without charge when returned prepaid to Stryker Instruments. There are no other expressed warranties. This warranty gives you specific legal rights and you may have other rights which vary by state and municipality.

For selected products.
- Universal Handswitch is warranted for a period of 6 months from date of invoice.
- Handpiece cords are warranted for a period of 6 months from date of invoice.
- Cutting accessories are not warranted.

European equiv. 5100-001-712
Japanese equiv. 5100-001-720
N. European equiv. 5100-001-733
Polish/Greek Equiv. 5100-001-750

stryker®

Instruments
4100 E. Milham
Kalamazoo, Michigan
(USA) 49001
1-800-253-321
1-269-323-7700

European Authorized Rep:
RA/QA Manager
Stryker France
ZAC Satolas Green Pusignan
Av. de Satolas Green
69881 MEYZIEU Cedex
France